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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,238	11/14/2001	Peter Battaglino	D0047 NP	5487

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/04/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,238

Applicant(s)

BATTAGLINO ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-48 is/are pending in the application.
- 4a) Of the above claim(s) 27,29,32,33,37-39,42,43,47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26,28,30,31,34-36,40,41 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group I drawn to a method of screening candidate compounds capable of modulating activity of a GPCR-encoded polypeptide, wherein the candidate compounds are small molecules, and the species of Group I containing a vector comprising the coding sequence of the beta lactamase gene under the control of NFTA response elements in Paper No. 10 filed on October 15, 2002 is acknowledged. The traverse is on the ground that Groups I II, and III are all embraced by a common generic claim and only the type of molecules identified by the generic method is different.

In view of applicants' argument, the Examiner has vacated the group restriction (Group I-III) set forth in previous office action in Paper No. 7. Therefore, the claimed invention drawn to a method of screening candidate compounds capable of modulating activity of a GPCR-encoded polypeptide, wherein the cells comprising a vector comprising the coding sequence of the beta lactamase gene under the control of NFTA response elements are currently under consideration.

The requirement is made FINAL.

2. Applicants' amendment in Paper No. 8 filed on 08/14/2002 has been entered in full. Claims 1-22 have been canceled. New claims 23-48 have been amended. Claims 23-26, 28, 30, 31, 34-36, 40, 41, and 44-46 are currently under consideration.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional applications, 60/248,285 (11/14/2000), 60/268,581 (02/14/2001), 60/308,285 (07/27/2001), and 60/317,166 (09/04/2001).

Drawings

4. The drawings filed on November 14, 2001 are accepted by the Examiner.

Rejections—35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 23-26, 28, 30, 31, 34-36, 40, 41, and 44-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 23-26, 28, 30, 31, 34-36, 40, 41, and 44-46 are drawn to a method of screening candidate compounds capable of modulating activity of a GPCR-encoded polypeptide set forth in SEQ ID NO: 2. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

The instant disclosure discloses a polypeptide set forth in SEQ ID NO: 2 and a polynucleotide sequence of SEQ ID NO: 1, which encodes the polypeptide. The disclosure further discloses information and data indicating the claimed polypeptide is a putative cell surface GPCR that can function through increase in either cAMP or Ca^{2+} signal transduction pathways via alpha 15.

However, such disclosure is insufficient to satisfy the utility requirement under 35 U.S.C. §101 because the ligand of the claimed polypeptide has not been disclosed and the specific biological function of the polypeptide are unknown. While members of GPCRs share certain characteristic structural motifs and features of signal transduction pathways, the biological function vary widely (see, e.g., Ji et al. G-protein-coupled receptors, *J. Biol. Chem.*, 273:17299-17302, 1998). Thus, without a defined ligand or biological function, one skilled in the art would not be able to recognize the specific and substantial use of the polypeptide of SEQ ID NO:2 and consequently the claimed method of screening for candidate compounds which modulate the activity of the polypeptide of SEQ ID NO:2.

The instant disclosure also asserts that the claimed invention provides methods for the treatment or prevention of cancers, immune disorders, or neurological disorders ([0026 of page 6]). The instant disclosure further asserts that the molecules of the present invention can be used for diagnosis of brain-related disorders or for monitoring response to therapy in humans (page 7). However, these asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The disclosure neither identifies the biological functions of

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the claimed proteins nor any disorders that are associated with the claimed molecules. Clearly, further research would be required to determine the functions of the claimed molecules or to identify a disease that can be treated or diagnosed with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Being a putative G-protein coupled receptor does not simply endow the polypeptide of the present invention because of the diversity of the structure and functions of the G-protein coupled receptors. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the compounds. Therefore, since the polypeptide of SEQ ID NO:2 does not have immediately practical application, a method of using the polypeptide for screening a modulator of the polypeptide consequently does not have a patentable utility.

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7. Claims 23-26, 28, 30, 31, 34-36, 40, 41, and 44-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the claimed method of screening candidate compounds were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 44 is drawn to a method of screening a candidate compound which is useful for treating disorders of the caudate nucleus. However, the instant disclosure fails to identify the biological functions of the claimed polypeptide, fails to demonstrate the existence of link established between the molecules of the present invention and disorders of the caudate nucleus, and fails to demonstrate the likelihood of the success of treating disorders of the caudate nucleus with a potential candidate compound. The instant disclosure fails to provide sufficient guidance,

information, or working examples on how to treat these neurological disorders. While the relative skill of those in the art is high in recombinant DNA technology and method of screening technology, successful treatment of the neurological disorders such as those recited in the claim remains a challenge. The prior art does not provide compensatory teachings to enable one skilled in the art to treat the broadly claimed disorders using a candidate screened by the claimed method.

Accordingly, the instant disclosure fails to enable such a claimed method of screening for a candidate compound which is useful for treatment of disorders of the caudate nucleus, it would require undue experimentation for one skilled in the art to make and use the claimed method embraced by the instant claim.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23-26, 28, 30, 31, 34-36, 40, 41, and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite because the steps of the method do not necessarily achieve the goal set forth in the claim preamble. It is unclear what is detected or measured that renders one able to select a candidate compound. Claims 24-26, 28, 30, 31, 34-36, 40, 41, and 44-46 depend from Claim 23.

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Claims 30 and 31 are indefinite because each claim recites "the polypeptide".

It is unclear whether it refers to SEQ ID NO:2, beta lactamase gene, or G alpha 15.

Claims 30 and 31 are indefinite also because each claim recites "high levels" or "low levels". It is unclear what the metes and bounds of the term are.

10. Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].


All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

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in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
November 29, 2002


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